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Application for Patent

C:47270

אני, (שם המבקש, מענ – ולגבי גוף מאוגד – מקום התאגדותו)
I (Name and address of applicant, and, in case of body corporate-place of incorporation)

NEOVASC MEDICAL LTD.
6 Yoni Netanyahu Street
Or Yehuda 60376

(An Israel company)

נאווסק מדיקל בע"מ
רחוב יוני נתניהו 6
אור יהודה 60376

(חברה ישראלית)

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VARYING-DIAMETER VASCULAR IMPLANT AND BALLOON
(באנגלית)
(English)

hereby apply for a patent to be granted to me in respect thereof מבקש בזאת כי ינתן לי עליה פטנט

*בקשה חלוקה - Application for Division	*בקשת פטנט מוסף - Application for Patent of Addition	*דרישה דין קדימה Priority Claim		
מבקשת פטנט from Application	*לבקשה/לפטנט to Patent/Appl.	מספר.סימן Number/Mark	תאריך Date	מדינת האיגוד Convention Country
No. מס.	No. מס.			
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רצוף בזה / ערד יוגש–*יפוי כח: כללי/מיוחד
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המען למסירת הודעות ומסמכים בישראל
Address for Service in Israel
סנפורד ט. קולב ושות'
ת.ד 2273
רחובות 76122

חתימת המבקש
Signature of Applicant

בשם המבקש

סנפורד ט. קולב ושות'

C:47270

היום 30 בחודש December שנת 2002
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VARYING-DIAMETER VASCULAR IMPLANT AND BALLOON

NEOVASC MEDICAL LTD.
C: 47270

נאווסק מדיקל בע"מ

VARYING-DIAMETER VASCULAR IMPLANT AND BALLOON

FIELD OF THE INVENTION

The present invention relates generally to implantable therapeutic devices, and specifically to varying-diameter intravascular implants.

BACKGROUND OF THE INVENTION

Stent implants are commonly used in treating arterial stenoses and other unwanted constrictions of body passages. Stents typically comprise a metal coil or mesh. An arterial stent, for example, is threaded through the vascular system to the point of stenosis in an artery. When the stent is in place, it is expanded to force the artery open to the desired diameter. Typically, the stent comprises a plastic material, which is inserted using a balloon catheter into the point of stenosis in a compressed state. The stent is then expanded by inflating the balloon. An apparatus and method for securing a stent to a balloon catheter is described, for example, in U.S. Patent 6,364,870, whose disclosure is incorporated herein by reference.

On the other hand, there are some procedures in which stent implants are required to constrict the diameter of a blood vessel. For example, Ruiz describes an endoluminal stent having adjustable constriction in U.S. Patent 6,120,534, whose disclosure is incorporated herein by reference. The stent comprises a deformable mesh having a conical portion and a constricted region, which forms a flow-limiting constriction. The stent is delivered and deployed inside a blood vessel. The constricted region of the mesh is then selectively enlarged to adjust the flow impedance in the vessel. Ruiz describes particularly the use of his stent to

reduce blood flow in the pulmonary artery, as a palliative treatment for infants having complex congenital cardiac malformations.

Other types of constricting stents and applications of such stents are described by Shalev et al. in PCT Patent Publication WO 01/72239, whose disclosure is incorporated herein by reference. In particular, this publication describes the use of a flow-reducing implant in the coronary sinus, in order to promote angiogenesis in the heart tissues. The implant is inserted by catheter through a central vein, such as the jugular vein, and brought into the coronary sinus. Alternatively, the implant may be installed in one or more of the coronary veins. Once the implant is in place, it is allowed to elastically expand or it is plastically expanded using a balloon.

Examples of high-pressure balloons, traditionally used in angioplasty, and recent balloon design development, are described in an article entitled, "Applications of High-Pressure Balloons for Medical Device Industry," *Medical Device and Diagnostic Industry Magazine* (September 2000), whose disclosure is incorporated herein by reference. Recent improvements in materials, balloon shape design, and fabrication technology include, *inter alia*, additional lengths, ultra thin walls (for minimal invasiveness and a smaller profile), varying diameters throughout the balloon length, custom shapes, and tapered ends and angles.

The specific shape of a high-pressure balloon may be demanded by the peculiarities of an anatomical site and/or the requirements of the treatment process. For example, a dog bone shaped balloon may be used to localize delivery of medication to avoid systemic

intravenous administration. The ends of the balloon can be of equal or different sizes, depending on the shape of the cavity or vessel. When inflated, the ends seal off the area to be treated, and the medication is infused through a hole or series of holes in the narrower center section of the balloon. High-pressure balloons are also used to position diagnostic devices inside vessels or body cavities for ultrasound imaging and other techniques. Rather than having a complicated steering or positioning mechanism on the end of a catheter, a high-pressure balloon can be used to either center or offset the device, precisely positioning it as required.

SUMMARY OF THE INVENTION

Embodiments of the present invention provide novel devices and methods for deploying an implant in a body passage, such as the coronary sinus, that varies in diameter over its length. In implantation of stents known in the art, a balloon whose diameter is roughly uniform over its length is typically used. Therefore, if the diameter of the body passage varies over the length of the stent, the end of the stent in the wider area of the passage may be insufficiently expanded, so that the stent is not securely anchored. Alternatively, the opposite end of the stent, in the narrower area of the body passage, may be expanded substantially beyond the natural diameter of the passage, causing strain on the tissue.

In embodiments of the present invention, on the other hand, the balloon that is used to expand the implant has a diameter that varies over its length, in such a way as to roughly match the varying diameter of the body passage. When the implant is in place within the body passage, the balloon is inflated to plastically expand the implant, so that the expanded diameter of the implant roughly matches the full diameter of the body passage at two or more points, typically at both ends of the implant. (In the case of a constricting implant, as may be used in the cardiac sinus in order to partially constrict the flow of blood therethrough, a part of the implant, typically a central part, may remain unexpanded.) As a result, the implant is anchored securely in place, without undue strain on the walls of the body passage.

The implant and balloon and method of inserting them described herein are particularly useful for restricting blood flow in the coronary sinus, as described in the

above-mentioned PCT publication and in U.S. Patent Application 09/534,968, which is assigned to the assignee of the present patent application and whose disclosure is incorporated herein by reference. The principles of the present invention, however, may be similarly used in deploying implants within other varying-diameter veins and arteries, as well as in other medical applications.

There is therefore provided, in accordance with an embodiment of the present invention, a method for deploying an expandable implant in a body passage of varying diameter, including:

selecting a balloon having a radial dimension that varies, when the balloon is inflated, in accordance with the varying diameter of the body passage;

inserting the balloon, in a deflated state, into the body passage, with the expandable implant fitted radially around the balloon; and

inflating the balloon so as to cause the implant to open, responsively to the varying radial dimension of the balloon, into an expanded shape that approximately matches the varying diameter of the body passage, thus anchoring the implant in the body passage.

Typically, the method includes attaching the balloon to a catheter and passing the balloon into the body passage using the catheter.

In one embodiment, the body passage is a coronary sinus of a patient, and passing the balloon includes:

guiding the catheter through a vascular path into a right atrium of the patient; and

steering the catheter within the right atrium so as to position the balloon and the implant in the coronary sinus.

Typically, the selected balloon has distal and proximal ends, and the radial dimension of the distal end

is substantially smaller than the radial dimension of the proximal end. Selecting the balloon may include measuring the diameter of the body passage at multiple points along the passage, and choosing the balloon from among a selection of available balloons, so as to fit the radial dimension of the balloon to the measured diameter of the body passage.

In one embodiment, in which the body passage is a coronary sinus of a patient, choosing the balloon includes fitting the balloon to a widening region of the coronary sinus adjacent to a right atrium of the patient. Typically, the implant includes a constriction, and inflating the balloon includes expanding the implant to match the varying diameter of the coronary sinus except at the constriction, so as to inhibit a flow of blood through the coronary sinus.

There is also provided, in accordance with an embodiment of the present invention, apparatus for treatment of a body passage of varying diameter, including:

a balloon having a radial dimension that varies, when the balloon is inflated, in accordance with the varying diameter of the body passage; and

an expandable implant, fitted radially around the balloon, so that when the balloon is inflated within the body passage, the implant opens, responsively to the varying radial dimension of the balloon, into an expanded shape that approximately matches the varying diameter of the body passage, thus anchoring the implant in the body passage. Typically, the apparatus includes a catheter, which is adapted to deploy the balloon and implant in the body passage.

Typically, the balloon is one of a plurality of balloons having different radial dimensions, which are

selectable for insertion into the body passage depending upon a measured diameter of the body passage at multiple points along the passage.

The present invention will be more fully understood from the following detailed description of the embodiments thereof, taken together with the drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A is a schematic, pictorial view of an exemplary implantable device, in a non-expanded position, in accordance with an embodiment of the present invention;

Fig. 1B is a schematic, pictorial view of the exemplary implantable device shown in Fig. 1A, in an expanded position;

Fig. 2 is a schematic, pictorial view of an exemplary stent balloon, in accordance with an embodiment of the present invention;

Fig. 3 is a schematic view of the vascular path to a human heart having a coronary sinus; and

Fig. 4 is a detailed schematic view of the coronary sinus following expansion of an implantable device by the balloon shown in Fig. 2, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

Reference is now made to Figs. 1A and 1B, which are schematic, pictorial views of an exemplary implantable device 100, in a constricted state and an expanded state, respectively, in accordance with an embodiment of the present invention. Device 100 is adapted for use particularly in restricting blood flow through the coronary sinus, as described in the above-mentioned PCT Publication WO 01/72239 and U.S. Patent Application 09/534,968. Alternatively, devices in accordance with the principles of the present invention may be implanted elsewhere in the vascular system, as well as in other body passages. For the sake of simplicity and clarity, however, and not limitation, embodiments of the present invention are described hereinbelow with reference to implantation of flow-constricting devices in blood vessels of varying diameter, such as the coronary sinus.

Device 100 is of general tubular construction with two expandable ends 110 and a central section 120. Further alternatively or additionally, device 100 may comprise a mesh or coil, as is known in the art. Device 100 comprises a deformable material, such as a suitable metal or plastic, as is known in the art of implantable devices, which is sufficiently flexible to be expanded by inflation of a balloon (shown in Fig. 2), but strong enough to hold its shape when it is deployed and expanded within a body passage, in the manner of stents known in the art. Furthermore, the shape of device 100, combined with its flexibility, enables the device to be deployed in compact form, as shown in Fig. 1A, and subsequently expanded, as shown in Fig. 1B, either partially or completely, within the coronary sinus. A non-expandable constricting element 125 may attached around a central

section 120 of device 100, in order to ensure that the central section remains constricted, as shown in Fig. 1B.

A flexible sleeve (not shown) may be fixed around or within device 100, in order to prevent blood from flowing through the openings in the sides of the device when it is implanted, so that substantially all the blood flows through central section 120. Typically, the sleeve comprises a biocompatible fabric such as Gore-Tex or Dacron, which is stitched or otherwise fastened to device 100. Alternatively, other sleeve materials may be used, such as thin plastic or rubber materials. Constricting element 125 is fitted around the sleeve, over central section 120. As can be seen in Fig. 1B, the effect of the constricting element is to maintain a predetermined reduced diameter of device 100 in the region of central section 120, defining a lumen with a constricted central section diameter. Constricting element 125 may comprise a closed ring, made of metal or plastic, or it may alternatively comprise a thread.

Reference is now made to Fig. 2, which is a schematic pictorial view of an exemplary high pressure stent balloon 200, used to expand device 100, in accordance with an embodiment of the present invention. Balloon 200 has a generally conical shape, having a blunt, narrowed distal end 210 and a widened proximal end 220. The balloon terminates in a taper 225, which forms a continuation of the channel portion of a catheter (shown in Fig. 4), through which the balloon is inflated and deflated. Balloon 200 typically comprises a high-pressure, non-elastic material, as is known in the art, which is designed to apply an outward radial force when inflated, as described in the above-mentioned article from *Medical Device & Diagnostic Industry Magazine*. Generally, device 100 is deployed into a body passage

with deflated balloon 200 contained concentrically within it. The shape of balloon 200 is adapted so that when balloon inflates, it expands device 100 and positions it within a preselected varying-diameter body passage, as is discussed hereinbelow.

Balloon 200 is typically fabricated from materials such as polyethlylene tererphthalate (PET) or nylon. Some considerations for fabricating balloon 200 using these materials include: high tensile strength, allowing high operating pressures; thin balloon wall formation, allowing precise balloon shape and low profile; and low elongation (otherwise known as "low compliance"). The latter consideration ensures that balloon 200, when fully pressurized, exhibits relatively unchanging dimensions, ensuring that device 100 is not uncontrollably over-expanded in a body passage. Low elongation also means that balloon 200 will not over-expand at either end of device 100 and that the expansion force of the balloon is directed generally radially to expand device 100 substantially against the walls of the body passage.

Reference is now made to Fig. 3, which is a schematic view of vascular paths to a human heart 300 having a coronary sinus 302. Coronary sinus 302 comprises a junction of three major cardiac veins (not shown), and becomes progressively wider as it empties into a right atrium 306. The diameter of coronary sinus 302 increases as it opens out into right atrium 306.

To implant device 100, the device is passed through the vascular system to a preselected position in coronary sinus 302, using a suitable percutaneous catheter (shown in Fig. 4). Suitable methods of catheterization for this purpose are known in the art. During the insertion procedure, device 100 is maintained in the non-expanded configuration shown in Fig. 1A, so that its outer

diameter is substantially smaller than the blood vessels through which it must pass, allowing the physician operating the catheter to pass the device through the blood vessels. Typically, the physician inserts the catheter through a jugular vein 310 or a subclavian vein 312, and then guides the catheter into a right atrium 306 via a superior vena cava 308. Another insertion point is through a femoral vein 322, and the catheter is then guided to an inferior vena cava 324 and into right atrium 306. Once in right atrium 306, the physician steers the catheter through a sharp bend in order to guide device 100 into coronary sinus 302.

Reference is now made to Fig. 4, which is a detailed schematic view of coronary sinus 302 following expansion of device 100 by balloon 200, in accordance with an embodiment of the present invention. A catheter 410 is used, as described hereinabove, to position the device and balloon in coronary sinus 302 via right atrium 306. Balloon 200 is then inflated, via catheter 410, and assumes a general shape as shown in the figure. The physician may choose the shape of balloon 200 in advance, so as to optimally match the given dimensions of the coronary sinus of the patient in question. These dimensions may be determined, for example, by taking fluoroscopic images while injecting a contrast agent into the coronary sinus, as is known in the art.

When balloon 200 is inflated, it applies a radial force to plastically expand device 100 against the walls of coronary sinus 302. As shown in the figure, due to the varying diameter of balloon 200, the distal end of device 100 is only partially expanded, whereas the proximal end of device 100 is more completely expanded, reflecting the varying diameter of coronary sinus 302. As previously noted, balloon 200 does not over-expand at

either end of device 100. Distal end 210 of balloon may protrude slightly from the distal end of device 100. In a similar fashion, widened proximal end 220 and the taper 225 of balloon 200 may protrude from the proximal end of device 100. Because the shape of device 100 is fit to the natural shape of the coronary sinus, both the distal and proximal ends of the device press outward against the wall of the coronary sinus with approximately equal force. Thus, device 100 is securely anchored in place, without exerting excessive pressure against the wall of the coronary sinus at any point. Central section 120, however, remains constricted due to the presence of constricting element 125 or other means provided for this purpose.

Once device 100 is satisfactorily positioned and expanded, balloon 200 is deflated and withdrawn from device 100. Catheter 410 and balloon 200 are then withdrawn from the body. Device 100 remains in place to restrict the flow of blood through coronary sinus 302. As noted above, this flow restriction increases the blood pressure in the coronary veins, thereby fostering angiogenesis. Device 100 may be left in place indefinitely, in substantially the form shown in Fig. 4. Alternatively, it may be desirable in some cases to eliminate the flow restriction caused by the device. In such cases, a catheter with a suitable cutting tool may be inserted percutaneously to the location of the device, and the cutting tool may then be used to cut constricting element 125 or central section 120. A balloon, such as balloon 200, may then be reinserted via catheter into device 100 and the balloon may then be inflated in order to open section 120.

Although in the embodiments described above, device 100 and balloon 200 are shown to have certain particular

shapes, alternative shapes and forms of these elements, which will be apparent to those skilled in the art, are considered to be within the scope of the present invention. Similarly, balloons of the general type described above may be used to deliver not only device 100, but also other implantable devices for implantation in other body passages of variable diameter, as are otherwise known in the art. Furthermore, although the catheter shown here provides a convenient means for delivering implantable devices in accordance with the present invention, balloons in accordance with the present invention may also be used in conjunction with other means for implant deployment, including both minimally invasive (typically percutaneous) and invasive (i.e., surgical) types.

It will thus be appreciated that the embodiments described above are cited by way of example, and that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof which would occur to persons skilled in the art upon reading the foregoing description and which are not disclosed in the prior art.

CLAIMS

1. A method for deploying an expandable implant in a body passage of varying diameter, the method comprising:

selecting a balloon having a radial dimension that varies, when the balloon is inflated, in accordance with the varying diameter of the body passage;

inserting the balloon, in a deflated state, into the body passage, with the expandable implant fitted radially around the balloon; and

inflating the balloon so as to cause the implant to open, responsively to the varying radial dimension of the balloon, into an expanded shape that approximately matches the varying diameter of the body passage, thus anchoring the implant in the body passage.

2. The method according to claim 1, wherein inserting the balloon comprises attaching the balloon to a catheter and passing the balloon into the body passage using the catheter.

3. The method according to claim 2, wherein the body passage is a coronary sinus of a patient, and wherein passing the balloon comprises:

guiding the catheter through a vascular path into a right atrium of the patient; and

steering the catheter within the right atrium so as to position the balloon and the implant in the coronary sinus.

4. The method according to claim 1, wherein the selected balloon has distal and proximal ends, and wherein the radial dimension of the distal end is substantially smaller than the radial dimension of the proximal end.

5. The method according to claim 1, wherein selecting the balloon comprises measuring the diameter of the body passage at multiple points along the passage, and choosing the balloon from among a selection of available balloons, so as to fit the radial dimension of the balloon to the measured diameter of the body passage.

6. The method according to claim 5, wherein the body passage is a coronary sinus of a patient, and wherein choosing the balloon comprises fitting the balloon to a widening region of the coronary sinus adjacent to a right atrium of the patient.

7. The method according to claim 1, wherein the body passage is a coronary sinus of a patient, and wherein the implant comprises a constriction, and wherein inflating the balloon comprises expanding the implant to match the varying diameter of the coronary sinus except at the constriction, so as to inhibit a flow of blood through the coronary sinus.

8. Apparatus for treatment of a body passage of varying diameter, the apparatus comprising:

a balloon, having a radial dimension that varies, when the balloon is inflated, in accordance with the varying diameter of the body passage; and

an expandable implant, fitted radially around the balloon, so that when the balloon is inflated within the body passage, the implant opens, responsively to the varying radial dimension of the balloon, into an expanded shape that approximately matches the varying diameter of the body passage, thus anchoring the implant in the body passage.

9. The apparatus according to claim 8, and comprising a catheter, which is adapted to deploy the balloon and implant in the body passage.

10. The apparatus according to claim 9, wherein the body passage is a coronary sinus of a patient, and wherein the catheter is adapted to be guided through a vascular path into a right atrium of the patient and to be steered within the right atrium, so as to position the balloon and the implant in the coronary sinus.

11. The apparatus according to claim 8, wherein the balloon has distal and proximal ends, and wherein the radial dimension of the distal end is substantially smaller than the radial dimension of the proximal end.

12. The apparatus according to claim 8, wherein the balloon is one of a plurality of balloons having different radial dimensions, which are selectable for insertion into the body passage depending upon a measured diameter of the body passage at multiple points along the passage.

13. The apparatus according to claim 12, wherein the body passage is a coronary sinus of a patient, and wherein the balloons are dimensioned to fit a widening region of the coronary sinus adjacent to a right atrium of the patient.

14. The apparatus according to claim 8, wherein the body passage is a coronary sinus of a patient, and wherein the implant comprises a constriction, such that after inflation of the balloon, the expanded shape of the implant approximately matches the varying diameter of the coronary sinus except at the constriction, so as to inhibit a flow of blood through the coronary sinus.

For the applicant,

Sanford T. Colb & Co.

C: 47270

FIG. 1A

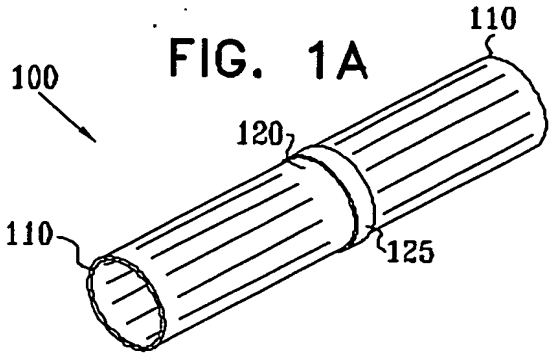


FIG. 1B

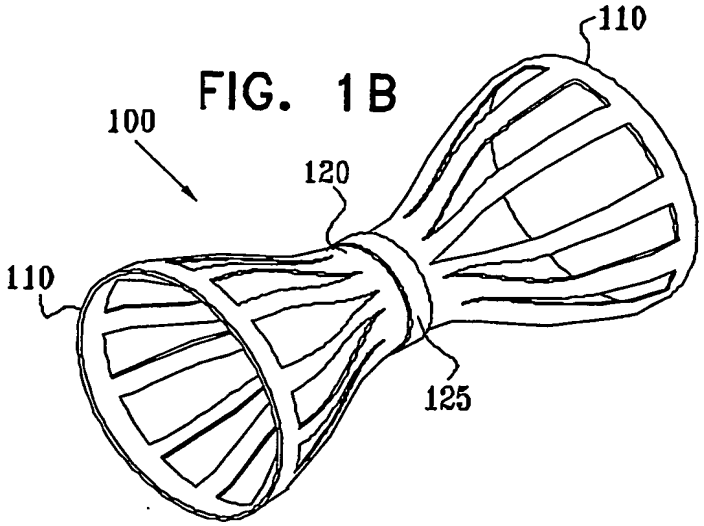
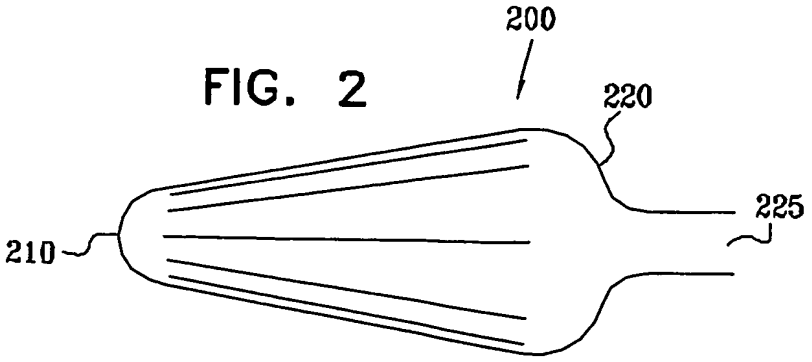


FIG. 2



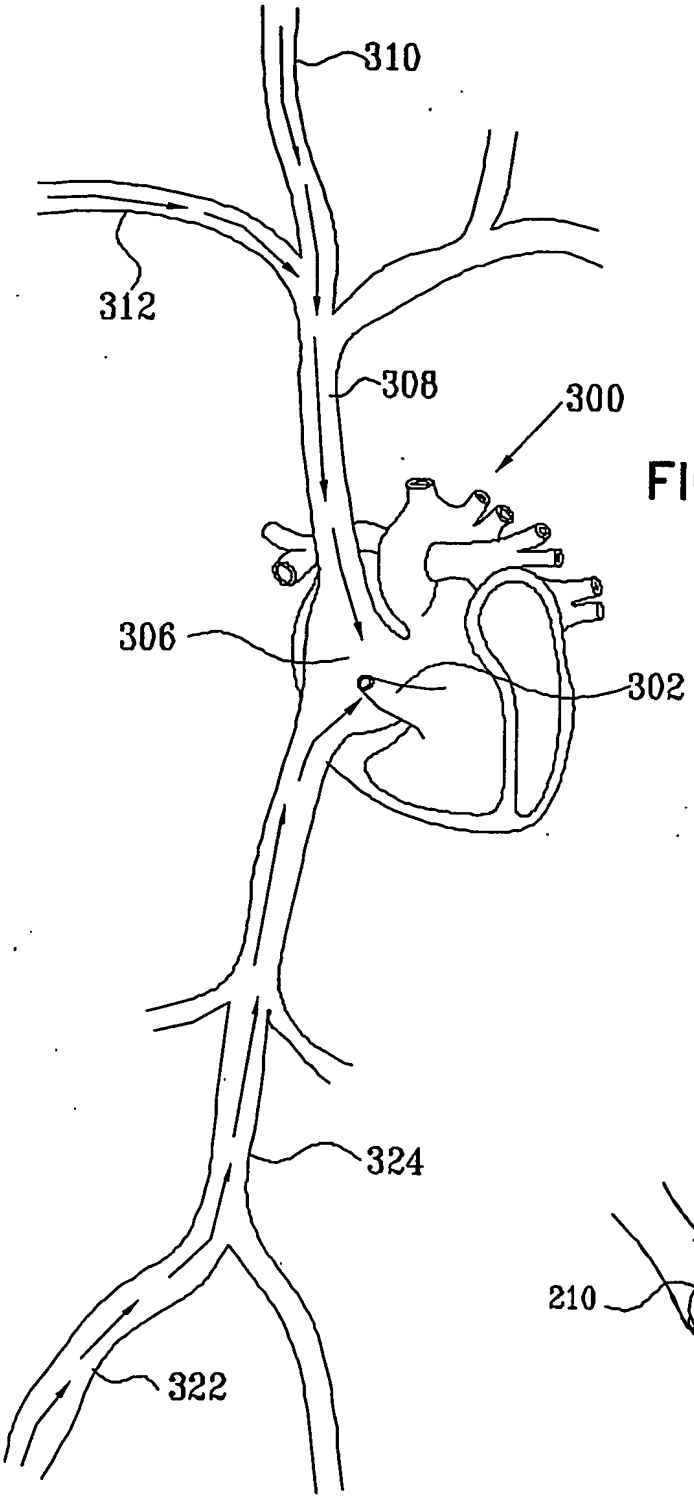


FIG. 3

FIG. 4